BACKGROUND

Sentinel is a program sponsored by the US Food and Drug Administration to monitor the safety of medical products. Prior epidemiologic studies reported a 67-90% greater risk of severe hypoglycemia associated with glyburide vs. glipizide.1,2 A systematic review of clinical trials found higher risk for glyburide compared to other secretagogues.3

OBJECTIVE

To evaluate the ability of the semi-automated, customizable Sentinel Propensity Score Matching (PSM) Tool to reproduce the increased risk of severe hypoglycemia seen in users of glyburide vs. glipizide in an expedited fashion

METHODS

Study Design: Retrospective cohort study

Data Source:

Sentinel Distributed Database (SDD)

Sentinel Distributed Partners (DPs) participated in this assessment

Study Population:

Individuals >= 18 years of age who initiated glyburide or glipizide between January 1, 2008 and September 30, 2014

RESULTS

All 13 DPs returned results for unmatched pre-defined PS and hdPS models and results for matched pre-defined PS models

Seven DPs returned results for matched hdPS models

Figure 2. Summary of results

Table 1. Incidence rate (IR) and hazard ratios (HR) of ED visits and hospital admissions for hypoglycemia

CONCLUSIONS

Our findings are consistent with the known higher rate of serious hypoglycemia with glyburide, and demonstrated the ability of the Sentinel PSM Tool to reproduce this known association in Sentinel

This study supports the utility of Sentinel to actively examine the safety of medical products